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cutting through complexity

Product serialization and traceability mandates

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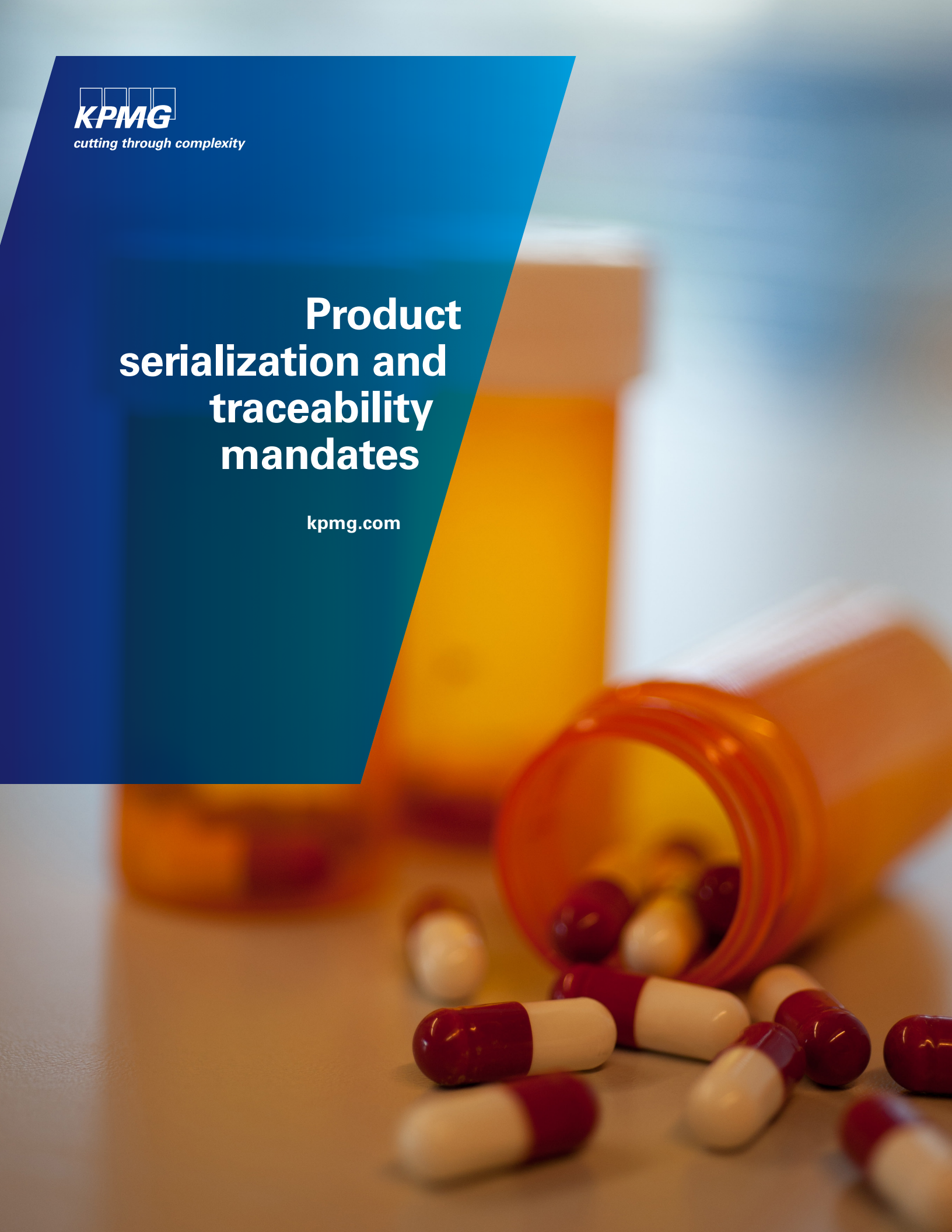


Increasing threats to patient safety from counterfeited, adulterated, and diverted pharmaceutical products have led to new regulations to secure the supply chain.

In an effort to battle the increasing threats to patient safety posed by counterfeited, adulterated, and diverted pharmaceutical products, regulatory agencies around the world are mandating new requirements to strengthen supply chain security.

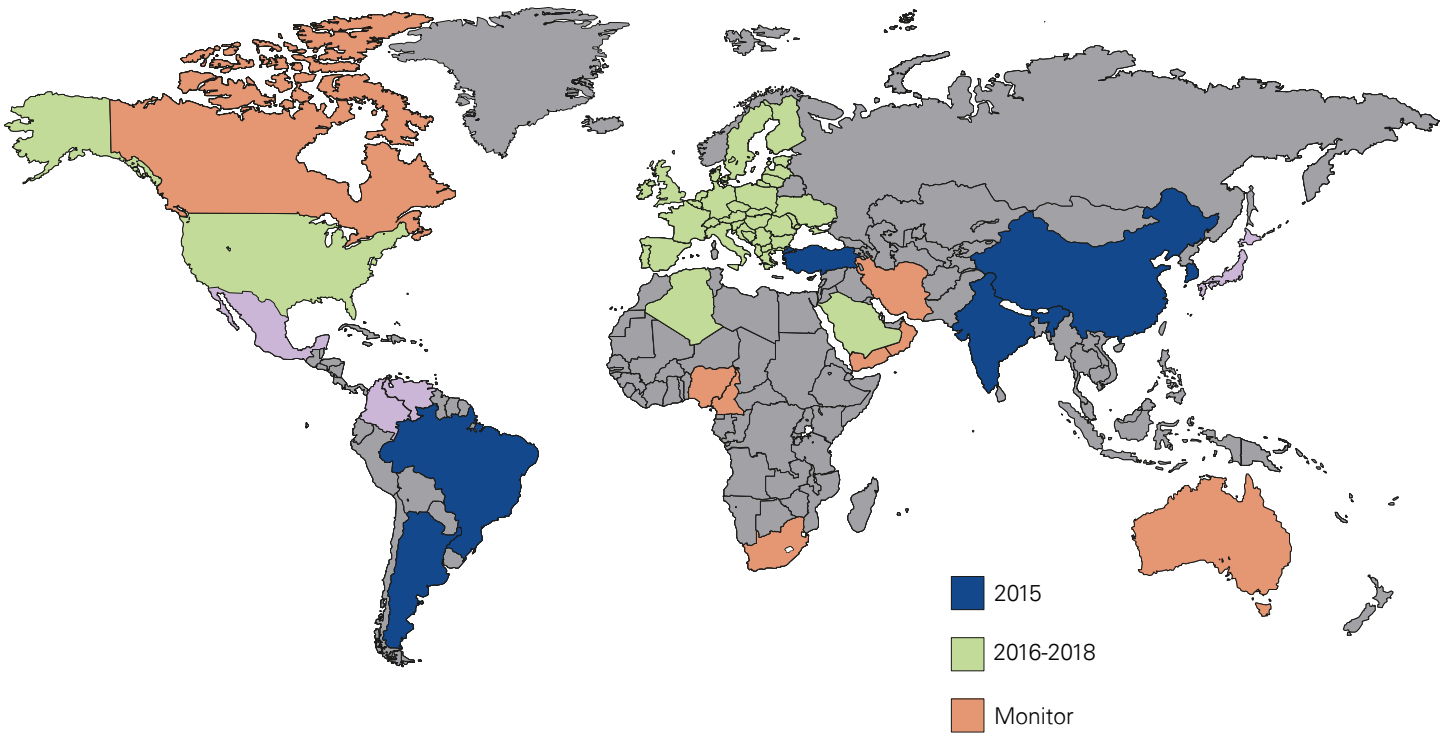
Here we provide an overview of new product serialization and traceability mandates developed to secure the distribution channel for all legitimate, regulation-approved prescription drug products. While common technical standards do exist for serialization and track-and-trace processes, there is presently no global regulation in place, and the application of standards vary by country and region applications vary by country/region.

Nevertheless, product serialization and traceability technologies and processes can be powerful tools in the increasingly complex effort to protect both patients and those dedicated to serving them.

Serialization mandates require manufacturer readiness

Despite historic efforts by law enforcement, industry, and the provider community, the patient safety issues resulting from adulteration of the supply chain have grown at an alarming rate.

These threats to patient safety have prompted action by governing regulatory agencies worldwide. There are current and pending requirements in numerous emerging and mature markets to mark each saleable unit (pack) with a unique serial number. Encoding the serial number involves a two-dimensional code called a data matrix and/or the more conventional linear bar code. Most countries are using coding and data standards from international organizations such as ISO (www.iso.org) and GS1 (www.gs1.org). However, exact specifications and applications of the standards vary by geography.



Global serialization regulatory snapshot
(Not a formal regulatory document)

This poses additional challenges for designing, operating, and supporting the implemented solutions and infrastructures.

Many markets require that each pack contain a physical serialized code, and that it be systematically tracked as ownership is transferred. This establishes a complete chain of custody for each salable pack from the first sale by the manufacturer (or marketing authorization holder), through each node of the supply chain, and ultimately to the hospital/pharmacy dispensing the prescription medication.

How serialization and traceability solutions are implemented will have a widespread impact in the life sciences sector. First, pharmaceutical and biotech companies, as well as the third-party packagers serving them, require investments in enterprise-level, manufacturing execution site-level, and packaging site and line-level technologies and infrasturctures.

Addressing these issues on multiple levels is necessary in order to allocate, encode, manage, and control serialization data. Second, wholesalers, specialty distributors, and third-party logistics (3PL) providers need to link product serial numbers to shipping and receiving transactions to maintain the flow of information throughout the distribution chain. Finally, in the future, pharmacies and healthcare providers will need automated data collection techniques. These will be used to verify product salability (serial number validity/status), automatically populate patient medical records, and enhance existing reporting capabilities for public health initiatives, such as adverse event tracking and recall management. Such requirements may come to fruition more quickly given market and consumer demands. For example, hospital patient bedside scanning and automated inventory management/billing may drive adoption, in addition to the need to comply with evolving regulatory requirements.

Example of linear bar code required by China FDA

Example of a 2-D data matrix

Costs and benefits of serialization and traceability

The business case for investing in a solution to enable pharmaceutical traceability should include more than basic compliance and avoidance of penalties and fines. Integrating serialized product data into major internal and external supply chain events should have value-added benefits. This is most important for manufacturers, as they face the most significant capital investments.

For example, linking individual product serial numbers to sales and distribution transactions allows for precise accounting and reconciliation of data that had not been possible or practical before. The following are three areas of potential opportunity:

1 Order-to-cash: Financial controls

- Sales price←→chargeback←→usage: Monitoring and reconciliation through serial numbers linked to each sales order
- Returned goods authentication with precise credit calculation based on serial number←→sales order usage

2 Inventory control and quality assurance

- Recall management and reporting, including scope and status tracking with wide-ranging visibility
- Stock rotation and expiration date management
- Increased accuracy in demand forecasting and supply planning activities

3 Logistics and cold chain management

- Linkage of serial numbers to temperature monitoring devices and shipping containers/envirotainers
- Targeted quarantine and usage decision related to impacted product for stock-level and shipment-level usage decisions

Challenges of serialization implementation

Despite potential value propositions, serialization can be a daunting organizational initiative. The biggest challenge may be implementing, operating, and maintaining serialization solution components in a cost-effective manner. Additionally, upgrades to Information Technology (IT) systems and infrastructure are considerable and complex, particularly when managing changes to standard product data entry, labeling and packaging, third-party packager integration, and distribution processes.

Other challenges and uncertainties include:

- Emerging market regulations that are unexpected or unclear
- Risk aversion within an organization
- Inconsistency and lack of interoperability across vendor technologies
- Insufficient experienced resources in this area
- Need to balance implementation with competing initiatives and product launches.

Three dimensions

Ultimately, both the challenges and opportunities presented by global serialization and traceability mandates can be categorized across the following three dimensions: people, process, and technology.

People

Across an organization, stakeholders involved in the implementation of serialization capabilities could represent, but are not limited to, the following functional areas:

- Regulatory affairs
- Quality assurance
- Supply chain
- Information technology
- Graphics/Label design
- Packaging engineering and operations
- Distribution
- Wholesaling
- Customer service
- Brand protection/marketing.

Further, the deployment of serialization and traceability solutions across an enterprise requires substantial organizational change. Effective change management initiatives, including adaptation, planning, collaboration, and communication across these functions, are critical success factors. There will likely be many new questions that require attention:

- Who owns the serialization data?
- Who needs access to it, and why?
- Who manages the serial numbers, and how do you obtain them?
- Who is responsible for updating the organization with regard to regulatory changes?

Process

Serialization initiatives require business and quality assurance functions to modify existing processes, policies, and procedures. Process impacts do not only stem from equipment technology. Existing processes are impacted and can be enhanced by such functional areas as quality assurance, supply chain, and customer service due to the additional serialization data that must be managed and controlled. This includes the following areas:

- Defect classification/in-process controls
- Batch release
- Deviation management and CAPA
- Product storage and distribution
- Pharmacovigilance (e.g., complaints management)
- Trading partner authorization/license verification.

Technology

Instituting product serialization can be challenging in light of the need for interoperable data exchange and business continuity across multiple organizations' ERP systems. IT infrastructure, manufacturing execution systems, packaging site and line technologies, and associated standard protocols are required for the following:

- Serial number storage in a secured repository within the enterprise and/or in a cloud-based system
- Serialization master and transactional data maintenance and control
- Retrieval of serial numbers from a repository as needed and appropriate to support ongoing operations
- Data transmission to supply chain partners and/or regulatory agency systems
- Printing and marking equipment for unique bar codes (1-D, 2-D data matrix)
- Using vision (camera) inspection stations to verify that bar codes and labels are printed accurately and meet quality standards
- Instituting automation controls for inspection, conveyor transport/sorting, and rejection stations
- Using mobile handheld devices with integrated scanners for transaction processing.

Serialization information and activities related to serial numbers require effective collaboration across all stakeholders and solution providers. Network performance must also be considered and thoughtfully engineered. Ultimately, serialization success hinges on the integrity and security of data for product tracking, which will ultimately rely on the speed and reliability of the system.

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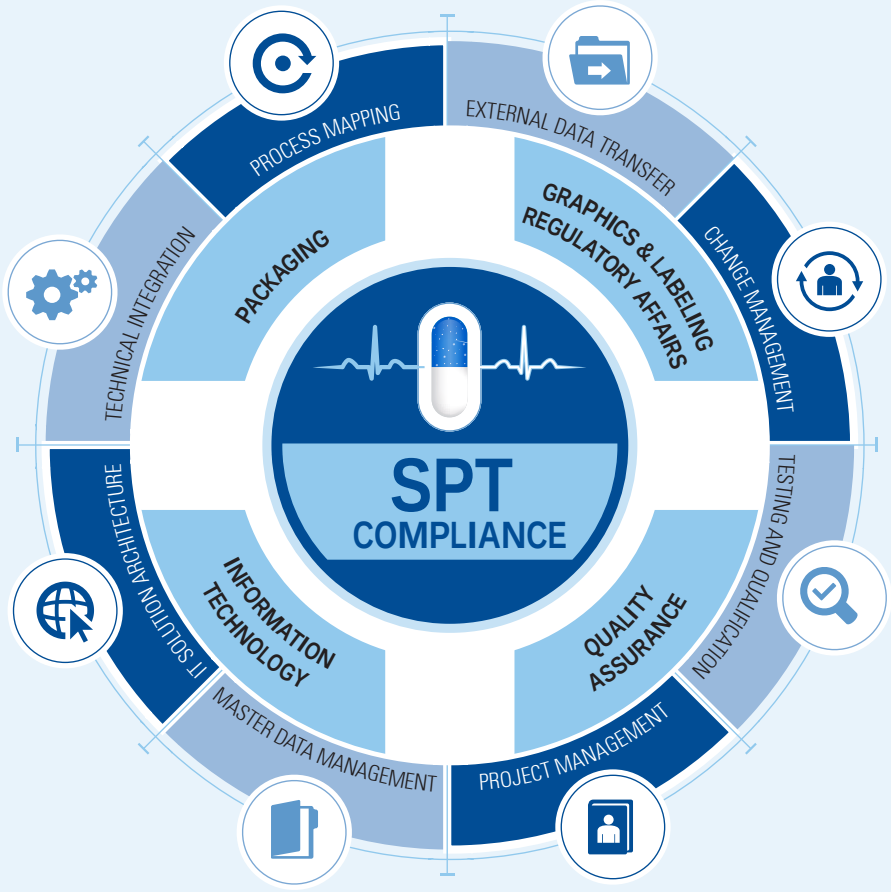

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